

Attn: ACF Reports Clearance Officer.  
Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2011-31871 Filed 12-12-11; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0847]

#### Draft Guidance for Industry and Food and Drug Administration Staff on Humanitarian Use Device Designations; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "Humanitarian Use Device (HUD) Designations." Devices are eligible for HUD designation if they are designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Devices that receive HUD designation may be eligible for marketing approval under the Humanitarian Device Exemption (HDE) marketing pathway. This guidance document is intended to assist applicants in the preparation and submission of HUD designation requests and FDA reviewers in evaluating such requests.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR

10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 12, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Orphan Products Development (OOPD), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Eric Chen, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5271, Silver Spring, MD 20993, (301) 796-8660.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Humanitarian Use Device (HUD) Designations." Devices are eligible for HUD designation if they are designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. (See section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)); 21 CFR 814.102). This guidance document is intended to assist applicants in the preparation and submission of HUD designation requests to FDA, OOPD. This guidance is also intended to assist FDA reviewers in the evaluation and analysis of HUD designation requests.

Topics addressed in this guidance include: (1) Demonstrating in HUD requests that the device is designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year; (2) how this demonstration varies, depending on whether the device is intended for therapeutic or diagnostic purposes; (3) how properties of the device may affect this demonstration; and (4) delineating a medically plausible subset of persons with a given disease or condition.

Devices that receive HUD designation may be eligible for marketing approval under an HDE application. An HDE application is a premarketing application that is similar to a premarket approval (PMA) application in that the applicant must demonstrate a reasonable assurance of safety, but in an HDE application, the applicant seeks an exemption from the PMA requirement to demonstrate a reasonable assurance of effectiveness. A device is eligible for HDE approval if, among other criteria, the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. (See section 520(m) of the FD&C Act; 21 CFR 814.104(b)(2)). Although a HUD designation is a prerequisite to submitting an HDE application, it is only one of many required elements of the application (21 CFR 814.104). Receipt of a HUD designation does not guarantee that the HDE marketing application will be approved.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on humanitarian use device designations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910-0332.

##### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 7, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-31867 Filed 12-12-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0813]

#### Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft report entitled "Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review" (literature review report). A literature review was conducted to address a requirement of the Patient Protection and Affordable Care Act (Affordable Care Act). FDA is publishing the literature review report to allow the public to provide comment on the report as it relates to the Affordable Care Act.

**DATES:** Submit either electronic or written comments on the literature review report by February 13, 2012.

**ADDRESSES:** You may submit comments, identified by Docket No. 2011-N-0813, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- Fax: (301) 827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Helen Sullivan, Office of Prescription Drug Promotion, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3263, Silver Spring, MD 20993-0002, (301) 796-1200, email: [helen.sullivan@fda.hhs.gov](mailto:helen.sullivan@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of a draft report entitled "Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review." A literature review was conducted to address section 3507<sup>1</sup> of the Affordable Care Act (see <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>). Section 3507(a) requires the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in standardized format (e.g., similar to "Drug Facts" on over-the-counter products) to the promotional labeling or print advertising of such drugs would "improve health care decisionmaking by clinicians and patients and consumers" (section 3507(a), Pub. L. 111-148, 124 Stat. 530). In making this determination, the law directs FDA to "review all available scientific evidence and research on decisionmaking and social and cognitive psychology" (section 3507(b), Pub. L. 111-148, 124 Stat. 530), and to consult manufacturers and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health.

To fulfill this requirement, FDA has commissioned an objective review of science-based studies related to the communication of quantitative benefit and risk information. FDA is making available the literature review report and is providing a comment period for interested parties to comment on the literature review report as it relates to section 3507 of the Affordable Care Act.

#### II. Electronic Access

Persons with access to the Internet may obtain the literature review report at <http://www.regulations.gov>.

#### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the literature review report. It is only necessary to

<sup>1</sup> Public Law, 111-148, 124 Stat. 119, 530 (codified at note following 21 U.S.C. 352).

send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document and labeled "ATTN: Literature Review." Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

All submissions received must include the agency name and docket number. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided.

Dated: December 8, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-31931 Filed 12-12-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Clinical Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the NIH Advisory Board for Clinical Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended to discuss personnel matters, the disclosure of which would constitute a clearly unwarranted invasion of privacy.

*Name of Committee:* NIH Advisory Board for Clinical Research.

*Date:* January 30, 2012.

*Time:* 10 a.m. to 1:15 p.m.

*Agenda:* To review the 2012 Clinical Center Strategic and Annual Operating Plan and provide updates on selected organizational initiatives.

*Place:* National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4-2551, Bethesda, MD 20892.

*Closed:* 1:15 p.m. to 2 p.m.

*Agenda:* To review and evaluate to discuss personnel matters.

*Place:* National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4-2551, Bethesda, MD 20892.

*Contact Person:* Maureen E Gormley, Executive Secretary, Mark O. Hatfield